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John Michael Leadbeater

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

DEES, NIKKI H

ART UNIT

PAPER NUMBER

1781

NOTIFICATION DATE

DELIVERY MODE

08/31/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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PPROCESSING@SUGHRUE.COM
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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/520,786 | Applicant(s) LEADBEATER ET AL. | |
| | Examiner Nikki H. Dees | Art Unit 1781 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-30 and 32-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-30 and 32-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 4, 2010, has been entered.

2. Claims 1, 2, 4-30, and 32-71 are currently pending in the Application. The previous objection to the specification has been withdrawn in view of the amendment to claim 44.

Claim Objections

3. Claim 43 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 43 depends from claim 39. In claim 39, "one layer comprises... tablet base material". Claim 43 requires

said one layer to further comprise tablet base material. As the “one layer” already comprises tablet base material, it is unclear how claim 39 further limits claim 43.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 4-30, and 32-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are to a tabletted chewing gum sweet, and a method for producing said chewing gum sweet. While the specification provides for the formulation of the chewing gum sweet, the specification does not provide specific guidance regarding the methods by which the chewing gum containing layer is to be granulated, or the parameters under which the sweet is to be compressed (e.g. pressures, times, temperatures), thus requiring an undue amount of experimentation on the part of the artisan to form the tabletted chewing gum sweet. In contrast, the prior art of Beringer, for example, teaches the conditions under which the gum base containing portion of a compressed tablet is to be granulated. However, it is believed that undue experimentation **would** be required to carry out the instantly claimed invention because

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there is **no** *direction or guidance presented* for granulating the gum base containing portion of the tablet, or the conditions under which the tablet is to be compressed, such as sizes, pressures, etc. Further, there is an **absence** of *working examples* concerning the methods of making the tablets.

In light of the above factors, it is seen that undue experimentation would be necessary to make and use the invention of claims 1, 2, 4-30, and 32-71.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35, 42, 49, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 35 claims a tabletted chewing gum sweet where one layer is thicker than the other. However, the ratio of thicknesses claimed includes 1:1, providing layers of the same thickness. From the claim, as written, it is unclear if the layers are to be different thicknesses, or if they may be the same thickness.

9. Claims 42, 49, and 56 are rejected for the same reason as applied to claim 35.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 2, 4-7, 12-30, 32-37, 39-44, and 71 are rejected under 35 U.S.C.

103(a) as being unpatentable over Beringer et al. (4,139,589).

12. Regarding claims 1, 2, 4, 20-22, 25, 33, 39, 40, 43, Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). The granulate material may be mixed in a number of ways, including mixing the chewing gum granulate with non-plastic tablet mass, followed by pelletizing (col. 2 lines 20-24; Example 12). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol).

13. The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8).

14. Regarding claims 12, 30, 32, and 44, the gum base is present at about 60% in Example 2 (col. 8). Example 4 comprises about 50% chicle (i.e. gum base) and Example 12 mixes granulated gum base with granulated tablet material, to provide 50% by weight or less gum base in the layer, depending on which "plastic" formulation is granulated.

15. Regarding claims 14, 15, 17-19, 36, 37, and 39, Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be

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different colors (col. 4 lines 8-12). The tabletted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient.

16. Regarding claim 16, Beringer et al. state that their product may have one layer that is hard and one layer that is plastic (col. 1 lines 31-34).

17. Regarding claims 23 and 24, Beringer et al. also prepare their layered tablet with an indentation. The first layer is compressed with an indentation. The second part (gum base) is added to the material. An additional layer is fed into the press and compressed to cover the plastic mass (gum base) inserted in the center (Fig. 6 and col. 5 lines 7-17).

18. Regarding claims 26-29, and 71, the tablet base material of Beringer et al. is sugar (Examples).

19. Beringer et al. are silent as to the layers having a different thickness and to the gum base material and tablet base material being particulated separately and compressed into a layer that is adjacent to a layer of tablet material.

20. However, Beringer et al. provide for their invention in a number of different arrangements. As Beringer et al. speak to granulating the tablet mass and chewing gum mass separately and combining them to be compressed (Example 12), as well as to the pellets comprising a plurality of interlayered or overlaid plastic masses, it would have been obvious to one of ordinary skill to have layered the first integral part comprising particulated gum base and particulated tablet material and the second

integral part comprising tablet base material in order to provide a tabletted chewing gum sweet comprising at least two integral parts.

21. Regarding claims 5-7, 13, 34, 35, 41, and 42, it would have been obvious for one of ordinary skill in the art at the time the invention was made to have varied the thickness of the layers as taught by Beringer et al. in order to provide more (or less) of one of the components of the tablet. As the thickness of the layers may be varied, the weight ratio of the layers may also be varied. The tablet as taught by Beringer et al. could be easily modified by one of ordinary skill without undue experimentation. There would have been a reasonable expectation that the resulting tablet would maintain its favorable chewing gum properties.

22. Regarding claims 20-22, Beringer et al. teach a process for making their layered tablet. The granulate material may be mixed in a number of ways, including mixing the chewing gum granulate with non-plastic tablet mass, followed by pelletizing (col. 2 lines 20-24). The chewing gum base may be mixed with the tablet base (Example 2, col. 8). The tablet mass is granular and pelletized. The granulate gum base is then pressed to the plastic (tablet base) portion of the tablet (col. 2 lines 3-11). Additional layers may be added as shown in Fig. 10 and col. 6 lines 30-45.

23. In the process of Beringer et al., the gum base and tablet material are mixed, granulated, and then compressed. Applicant's claims are to the particulated gum base and particulated tablet material presented separately, mixed, and then compressed. The selection of any order of performing process steps is considered to be *prima facie* obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690,

69 USPQ 330 (CCPA 1946). In the instant case, both the method of Beringer et al. and the claimed method result in a particulate material that is compressed into a tablet. As this result is neither new nor unexpected, the claimed process is considered to be obvious over the prior art.

24. Claims 8-10, 53, and 55-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805).

25. Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol). The gum base is present at about 60% in Example 2 (col. 8).

The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8). Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be different colors (col. 4 lines 8-12).

The tabletted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient.

26. Beringer et al. are silent as to the same sugar or polyol being used as the tablet base in both the first (gum base) and second (outer layer) of their invention. Beringer et

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al. are silent as to the use of a plasticized rubber or polymer for the gum base. They are also silent as to their invention containing a dental vehicle or breath freshener.

27. Cherukuri et al. teach a tabletted chewing gum composition that is made by compression (Abstract). Their invention is taught with both a nutritive sweetener (sugar) and sugar-free using sorbitol (col. 11 Examples IV and V). Cherukuri et al. teach a number of compounds that may be use for the gum base including polymers (col. 6 lines 14-20). They also teach their invention comprising fluorides for tooth decay (col. 9 lines 34-35) and flavoring agents including spearmint oil and oil of wintergreen (col. 8 line 1).

28. Regarding claims 8 and 10, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polyol as taught by Cherukuri et al. along with gum base, as well as in the outer layers as taught by Beringer et al. Beringer et al. teach the use of sorbitol in the outer layer (Example 2) and Cherukuri et al. teach the use of sorbitol blended with the gum base for the production of a tabletted chewing gum. One of ordinary skill desiring to produce a sugar free product would be able to substitute sorbitol for the sugar in the invention of Beringer et al. This would not have required undue experimentation on the part of the artisan, and the resultant sugar-free product would have been expected to maintain its favorable taste and chewing properties.

29. Regarding claims 9 and 53, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a chewing gum base other than the chicle as taught by Beringer et al. One of ordinary skill would have been

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familiar with other gum bases as taught by Cherukuri et al. and would have been able to substitute a different gum base for the chicle without undue experimentation in order to impart the desired "chewiness" in their product. There would have been a reasonable expectation that the resultant product would have maintained its favorable chewing properties.

30. Regarding the different colors providing contrasting effects, the selection of colors for the different layers is considered an obvious matter of choice depending on the effects one of ordinary skill wishes to convey. As Beringer et al. teach that the layers of their product may be different colors, the selection of contrasting colors is considered obvious and not considered to provide any patentable distinction over the teachings of the prior art.

31. Regarding claims 65-66, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the flavoring agents and fluorides to prevent tooth decay as taught by Cherukuri et al. with the chewing gum composition as taught by Beringer et al. The composition of Beringer et al. is taught comprising other pharmaceutical agents, though not the specific ones as claimed. One of ordinary skill could have taken the additional components as taught by Cherukuri et al. and added them to the composition of Beringer et al. without undue experimentation. The resultant product would have been expected to have the desired dental vehicle or breath freshening properties while still maintaining its favorable chewing and taste properties.

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32. Claims 11, 38, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Fisher et al. (4,370,350).

33. Beringer et al. teach a layered tablet chewing gum product as applied to claims 1, 25, and 39 above.

34. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

35. Fisher et al. teach a tabletted chewing gum product made by compression (col. 1 lines 65-67). They go on to state that the particles being compressed passed through a 20 to 80 mesh screen (177 μm to 841 μm) and easily tableted on conventional machinery (col. 4 lines 56-58).

36. Regarding claims 11, 38, and 45, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the particle size as taught by Fisher et al. for the production of the tabletted chewing gum product of Beringer et al. The products are being produced by the same technology, and Fisher et al. state that they have favorable results when tableting their product. Therefore, it would have been obvious to use the same particle size in the layered product of Beringer et al. There would not have been undue experimentation required to make this modification to the product of Beringer et al., and the resultant tablets would have been expected to maintain their chewing and flavor characteristics.

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37. Claims 46-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805) and in further view of Fisher et al. (4,370,350).

38. Beringer et al. in view of Cherukuri et al. teaches a gum base in the form of polymers as detailed above.

39. Beringer et al. in view of Cherukuri et al. is silent as to the size of the particles to be compressed.

40. Regarding claims 46-52, the product of Beringer et al. is taught as having multiple layers of the same thickness as detailed above. The product also comprises about 60% of gum base (chicle) and the layers may be different colors, also as detailed above.

41. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

42. Fisher et al. teach a tabletted chewing gum product made by compression comprising particles ranging in size from 20 to 80 mesh (177 μm to 841 μm) as noted above.

43. Motivation for combining Beringer et al. and Fisher et al. in respect to claims 46-52 and 54 is the same as the motivation as applied above to claims 11 and 38. One of ordinary skill in the art would have expected this combination to result in a favorable chewing gum tablet.

44. Regarding claim 49 and the varying of the thickness of the layer, motivation for the variations in these thicknesses are the same as applied to claims 5-6 above. The

adjustment of the thickness of the layers would not have required undue experimentation, and would not have adversely affected the efficacy of the product.

Response to Arguments

45. Applicant's arguments filed February 4, 2010, have been fully considered.

46. The arguments are persuasive with regard to the teachings of Beringer anticipating the instant claims. However, the Examiner maintains that the teachings of Beringer render the instant claims obvious as detailed in the rejection *supra*.

47. Applicant argues (Remarks, p. 18) that Beringer does not provide an enabling disclosure of chicle content of 60%.

48. This argument is not persuasive. The Examiner has cited the specific examples in Beringer where this, and other, chicle (i.e. gum base) content can be found. The Examiner notes that the components listed by Beringer in for example, the plastic mass of Example 2, do not add up to 100. However, this is not sufficient to consider the teachings of Beringer as not enabling for the production of the plastic mass. The Examiner notes that Example 2 of Applicant's specification provides for 245.95 parts of gum/sorbitol premix to be combined with lubricant, flavors, and colors, for a total of 250.1 parts. Clearly, it is not uncommon in the art to list components such that the total does not add up to 100 parts.

49. Applicant argues repeatedly that the Examiner relies on hindsight to arrive at the instant invention (Remarks, pp. 19, 24).

50. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

51. Clearly, as detailed in the rejection, Beringer, and Beringer in combination with Fisher and Cherukuri, provide for all limitations of Applicant's claimed invention. Certainly, the instant invention of a multi-layer tablet where the layers comprise different amounts of gum base and tablet material was well within the level of ordinary skill at the time the invention was made based on the teachings of the cited prior art.

52. Applicant argues that Beringer does not teach any method as required by instant claim 20 (Remarks, p. 21).

53. As noted in the rejection, Beringer clearly teaches the mixing of granulated chewing gum material and granulated tablet material before compression. Beringer further teaches the production of layered tablets, wherein the different layers comprise varying amounts of tablet material, plastic material (i.e. gum base) and active

ingredients. Therefore, it cannot be said that Beringer is “wholly immaterial” to pending claim 20. Rather, upon reading Beringer the artisan would have a clear understanding of the production of multi-layer tablets, and find any rearrangement of the layers of the tablet as obvious over the teachings of Beringer.

54. Applicant argues (Remarks, p. 22) that the disclosure of Beringer is not enabling for actually producing the compressed chewing gum tablets of the invention.

55. This argument is not persuasive. First, none of the limitations as recited (i.e. sizes, pressures, times, temperatures, etc.) are required in the instant claims. Further, it is importantly noted that the limitations which Applicant argues that Beringer does not teach and therefore would allegedly involve a “huge amount of creativity and experimentation” by the artisan, are actually not taught in Applicant’s own specification. Therefore, by Applicant’s reasoning, Applicant’s own specification is not enabling for Applicant’s claimed invention. Consequently, applicant is referred to the rejection above under 35 USC 112 1st.

56. Applicant continues to argue that Beringer “prefers” the use of a pre-cut disc of plastic mass (i.e. gum base) in the tablet of their invention (Remarks, p. 23).

57. This argument is not persuasive. “[T]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed.

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Cir. 2004). Nowhere does Beringer state that the precut disc is preferred. Indeed, Beringer clearly teaches tablets comprising a layer of granulated chewing gum mass, as shown by Fig. 10 and taught at col. 6 lines 30++.

58. Applicant argues that the gum base of Beringer is “plastic”, not “elastic” (Remarks, p. 24).

59. This argument is not persuasive. The Examiner is unclear as to where there is any requirement that the gum base of the instant invention be “elastic” rather than “plastic.” The word “elastic” does not appear anywhere in the instant specification that would define the instant gum bases over that of the prior art.

60. Applicant further argues that “the example” is of “pure” gum base (Remarks, p. 24).

61. This argument is not persuasive. It is unclear to what “example” Applicant is referring. Further, none of the examples in Beringer are “pure” gum base. All examples comprise ingredients in combination with the chicle gum to provide the plastic mass.

Conclusion

62. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Examiner has included NPL for the product Razzles. Razzles appear to be a compressed tablet that, upon chewing, Razzles are first candy, then gum, indicating that they are a mixture of compressed gum base and tablet base.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-4:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. D./

Nikki H. Dees
Examiner
Art Unit 1781

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781